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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/439,740	11/15/99	FUNK W	UVI-005CP2CN

000959
LAHIVE & COCKFIELD
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HM12/0509

EXAMINER	
BUGAISKY,G	

ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/439,740	FUNK et al.
Examiner	**Art Unit**
Gabriele E. Bugaisky	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 15, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-60* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☒ Claim(s) *32-37 and 41-54* is/are allowed.

6) ☒ Claim(s) *27-31, 38-40, and 55-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group II in Paper No. 9 and cancellation of claims directed to Group I is acknowledged.

Claims 27-60 are currently pending.

Drawings

The drawings are objected to by the draftsman, as summarized on the enclosed PTO-948.

Specification

The disclosure is objected to because of the following informalities: The paper filed 6/8/00 amended the specification by inserting all of the continuing information prior to first line. The amendment did not, however, cancel the information on lines 8-10 of page 1, which presented the prior applications related to application 08/175,168. This latter information is now redundant.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-30 and 55-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Funk *et al.* The reference provides for expression of the amino terminal half of human serum transferrin by transformed eukaryotic cells, and is deemed to be an invention by others because the inventive entity is not identical to the authorship of the reference.

Claims 27-30, 38-40 and 55-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodworth *et al.* The reference provides for expression of the amino terminal half of human serum transferrin by transformed eukaryotic cells, in the expression vector pNUT and thus anticipates claims 27-30 and 55-60. A site directed mutant at D_{63} is also disclosed and thus anticipates claims 38-40 and 55-60.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-31 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman *et al.* in view of Woodworth *et al.* Bowman teaches the cloning of human serum transferrin, and differs from the instant invention in that expression of the cloned gene was not accomplished. The reference does point out (column 2, lines 45-52 and column 3, lines 41-52) that the gene can be placed into a eukaryotic expression vector. Woodworth *et al.* provide for expression of the amino terminal half of human serum transferrin by transformed eukaryotic cells, but do not provide for the expression of full-length transferrin In order to express full length transferrin or the carboxyl terminus of the transferrin gene of Bowman *et al.*, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the expression system of Woodward *et al.* with a reasonable expectation of success in obtaining eukaryotic expression of recombinant human serum transferrin free from any other human proteins.

-continued

(2) INFORMATION FOR SEQ ID NO:7:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 6 amino acids
(B) TYPE: amino acid
(D) TOPOLOGY: linear

(ii) MOLECULE TYPE: peptide

(v) FRAGMENT TYPE: internal

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:7:

Val Pro Asp Lys Thr Val
1 5

We claim:

1. A recombinant human serum transferrin mutant, wherein at least one of Asn413 and Asn611 of SEQ ID NO:2 are mutated to an amino acid which does not allow glycosylation.

2. A recombinant human serum transferrin C-terminal lobe mutant, wherein at least one of Asn413 and Asn611 of SEQ ID NO:2 are mutated to an amino acid which does not allow glycosylation.

3. The mutant of claim 2, wherein the C-terminal lobe comprises amino acids 343–679 of SEQ ID NO:2.

4. The mutant of any of claims 1–3, wherein at least one of Asn413 and Asn611 of SEQ ID NO:2 are mutated to an aspartic acid.

5. The mutant of any of claims 1–3, wherein Asn413 and Asn611 of SEQ ID NO:2 are mutated.

6. The mutant of claim 5, wherein Asn413 and Asn611 of SEQ ID NO:2 are mutated to aspartic acid.

7. A recombinant human serum transferrin mutant having a mutation in at least one amino acid residue selected from the group consisting of Asp63, Gly65, Tyr95, Tyr188, His249, Asp392, Tyr426, Tyr517 and His585 of SEQ ID NO:2, wherein the mutant retains the ability to bind metal.

8. A recombinant human serum transferrin N-terminal lobe mutant having a mutation at Asp63 or Gly65 of SEQ ID NO:2, wherein the mutant retains the ability to bind metal.

9. The mutant of claim 7 or 8, wherein Asp63 of SEQ ID NO:2 is mutated.

10. The mutant of claim 9, wherein Asp63 is mutated to serine.

11. The mutant of claim 7 or 8, wherein Gly65 of SEQ ID NO:2 is mutated.

12. The mutant of claim 11, wherein Gly65 is mutated to arginine.

13. A recombinant human serum transferrin mutant having a mutation at Lys206 or His207 of SEQ ID NO:2, wherein the mutant has a stronger binding avidity for metal than wild-type human serum transferrin.

14. A recombinant human serum transferrin N-terminal lobe mutant having a mutation at Lys206 or His207 of SEQ ID NO:2, wherein the mutant has a stronger binding avidity for metal than wild-type N-terminal lobe of human serum transferrin.

15. The mutant of claim 13 or 14, wherein Lys206 of SEQ ID NO:2 is mutated.

16. The mutant of claim 15, wherein Lys206 is mutated to glutamine.

17. The mutant of claim 13 or 14, wherein His207 of SEQ ID NO:2 is mutated.

18. The mutant of claim 18, wherein His207 is mutated to glutamic acid.

19. A recombinant human serum transferrin mutant having a mutation at Lys206 and His207 of SEQ ID NO:2, wherein the mutant has a stronger binding avidity for metal than wild-type human serum transferrin.

20. A recombinant human serum transferrin N-terminal lobe mutant having a mutation at Lys206 and His207 of SEQ ID NO:2, wherein the mutant has a stronger binding avidity for metal than wild-Type N-terminal lobe of human serum transferrin.

21. The mutant of claim 19 or claim 20, wherein Lys206 is mutated to glutamine and His207 is mutated to glutamic acid.

22. The mutant of claim 7 or 13, wherein at least one of Asn413 and Asn611 of SEQ ID NO:2 is mutated to amino acid which does not allow glycosylation.

23. The mutant of claim 22, wherein at least one of Asn413 and Asn611 are mutated to aspartic acid.

* * * * *

Conclusion

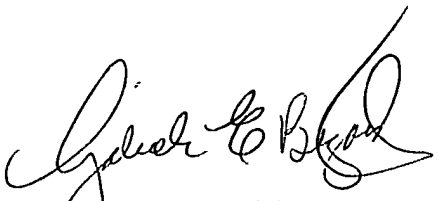
Claims 32-37 and 41-54 are allowed. The specifically recited site directed mutants are free of the prior art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 5:50 AM to 11:50 AM on Mondays and from 8:00 AM to 2:00 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



Gabriele E. Bugaisky
Patent Examiner
May 7, 2001